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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 20

Complete if Known

Application Number	10/527,672
Filing Date	April 18, 2006
First Named Inventor	RAPPUOLI
Group Art Unit	1645
Examiner Name	Devi
Attorney Docket Number	002441.00121

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		ABBAS et al., <u>Cellular and Molecular Immunology</u> , 4th ed., Chapter 15, pages 360-62, 2000	
		AMARA et al., "Molecular detection of methionine in rat brain using specific antibodies," <u>Neurosci. Lett.</u> 185, 147-50, February 13, 1995	
		ARESCOUG et al., "Group B streptococcal surface proteins as targets for protective antibodies: identification of two novel proteins in strains of serotype V," <u>Inf. Immun.</u> 67(12), 6350-57, Dec. 1999	
		BANKS et al., "Progress toward characterization of the Group A Streptococcus metagenome: Complete genome sequence of a macrolide-resistant serotype M6 strain," <u>J. Infectious Diseases</u> 190, 727-38, August 15, 2004	
		BARNETT & SCOTT, "Differential recognition of surface proteins in Streptococcus pyogenes by two sortase gene homologs," <u>J. Bacteriol.</u> 184, 2181-91, 2002	
		BARNETT et al., "A Novel Sortase, SrtC2, from Streptococcus pyogenes Anchors a Surface Protein Containing a QVPTGV Motif to the Cell Wall," <u>Journal of Bacteriology</u> , Vol. 186, No. 17, pp. 5865-5875, September 2004	
		BECKMANN et al., "Identification of Novel Adhesins from Group B Streptococci by Use of Phage Display Reveals that C5a Peptidase Mediates Fibronectin Binding," <u>Inf. Immun.</u> 70, 2869-76, June 2002	
		BESSEN et al., "Genomic Localization of a T Serotype Locus to a Recombinatorial Zone Ending Extracellular Matrix-Binding Proteins in Streptococcus pyogenes," <u>Infection and Immunity</u> , Vol. 70, No. 3, pp. 1159-1167, March 2002	
		BLACK et al: "Streptococcus pneumoniae polypeptide coding region"; GENBANK Accession No. AAV42990, November 9, 1998.	
		BLACKBURN et al., "The end of the (DNA) line," <u>Nature Structural Biology</u> 7, 847-49, Oct. 2000	

Examiner
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		BORK et al., "Powers and pitfalls in sequence analysis: the 70% hurdle," Genome Research 10, 398-400, 2000	
		BOROVEC et al., "Synthesis and assembly of hepatitis A virus-specific proteins in BS-C-1 cells," J. Virol. 67, 3095-301, June 1993	
		BOWIE et al., "Deciphering the message in protein sequences: tolerance to amino acid substitution," Science 257, 1306-10, 1990	
		BRODEUR et al., "Identification of group B streptococcal Sip protein, which elicits cross-protective immunity," Inf. Immun. 68(10), 5610-8, Oct. 2000	
		BURGESS et al., "Possible dissociation of the heparin-binding and mitogenic activities of heparin-binding (acidic fibroblast) growth factor-1 from its receptor-binding activities by site-directed mutagenesis of a single lysine residue," J. Cell Biol. 111, 2129-38, 1990	
		CHUNG et al., "chlorosome protein," NCBI Accession No. 2115394F, July 10, 1992	
		CLANCY et al., "Cloning and Characterization of a Novel Macrolide Efflux Gene, mreA, from Streptococcus agalactiae," Antimicrobial Agents and Chemotherapy 41, 2719-23, 1997	
		COLLINS et al., "Mutation of the principal sigma factor causes loss of virulence in a strain of the Mycobacterium tuberculosis complex," Proc. Natl. Acad. Sci. USA 92, 8036-40, 1995	
		DALE et al., "New Protective Antigen of Group A Streptococci," J. Clin. Invest. 103, 1261-68, May 1999	
		DALE et al., "Recombinant, octavalent group A streptococcal M protein vaccine," Vaccine 14, 944-48, 1996	

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		DALE, "Group A Streptococcal Vaccines," Infectious Disease Clinics of North America 13, 227-43, March 1999	
		DALE, "Multivalent group A streptococcal vaccine designed to optimize the immunogenicity of six tandem M protein fragments," Vaccine 17, 193-200, 1999	
		DATABASE EMBL, Accession No. AAX13129, Enterococcus faecalis genome contig SEQ ID No: 192, March 19, 1999	
		DATABASE EPO Proteins, EBI Accession No. AX605513, "Sequence 3442 from WO0209818," February 17, 2003	
		DATABASE Geneseq, "Group B Streptococcus protein sequence SEQ ID NO:49," EBI Accession No. GSP:AAY91320, May 30, 2000	
		DATABASE Geneseq, "Streptococcus agalactiae protein, SEQ ID 2382," EBI Accession No. GSP:ADV81242, February 24, 2005	
		DATABASE Geneseq, "Fibrinogen-binding polypeptide, SEQ ID NO:17," EBI Accession No. GSP: ADS93952, December 2, 2004; revised in 2007	
		DATABASE Geneseq, EBI Accession No. GSP: ABP30134, "Streptococcus polypeptide SEQ ID NO:9444," July 2, 2002	
		DATABASE Geneseq, EBI Accession No. GSP: ABP27285, "Streptococcus polypeptide SEQ ID NO:3746," July 2, 2002; revised in 2007	
		DATABASE Geneseq, "Protein encoded by Prokaryotic essential gene #319788," Accession No. ABU46451, June 13, 2003	

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		DATABASE JPO Proteins, "Nucleic acid and protein originating in group B Streptococcus," EBI Accession No. JPOP:BD629260, July 17, 2003	
		DATABASE SWISSPROT[Online] 01 Oct 2002, accession no. EBI, Database accession no. Q9PGX9, Hypothetical protein XF0167	
		DATABASE UniProt [Online] 1 March 2003, "Cell wall surface anchor family protein," retrieved from EBI accession no. UNIPROT: Q8DYR5, Database accession no. Q8DYR5, 87.2% identity with SEQ ID NO:20906	
		DATABASE UniProt [Online], 22 November 2005, "Cell wall surface anchor family protein," retrieved from EBI accession no. UNIPROT: Q3D2D6; 100% identity with SEQ ID NO:20906; abstract	
		DE BOEVER et al., "Enterococcus faecalis conjugative plasmid pAM373. Complete nucleotide sequence and genetic analyses of sec pheromone response," Mol. Microbiol. 37, 1327-41, 2000	
		DITTMER et al., "Treatment of infectious diseases with immunostimulatory oligodeoxynucleotides containing CpG motifs," Curr. Opin Microbiol. 6, 472-77, Oct. 2003	
		DUEZ, "Enterococcus hirae mraR, pbp3s, mraY, murD, murG, ftsQ and ftsA genes, mraW, yllC and ftsZ partial genes," GENBANK Accession No. Y13922, April 18, 2005	
		ELLIS, <u>Vaccines</u> , Chapter 29, Plotkin et al., eds., W.B. Saunders Company (Philadelphia), pages 568-75, 1988	
		EXAMINATION REPORT for NZ 560966, March 4, 2009, 2 pages	
		FERRETTI et al., "Complete genome sequence of an M1 strain of Streptococcus pyogenes," Proc. Natl. Acad. Sci. USA 98, 4658-63, April 10, 2001	

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		FERRETTI et al., "Putative surface exclusion protein," GENBANK Accession No. Q9A1H3, October 31, 2006	
		FERRETTI et al: "Streptococcus pyogenes M1 GAS strain SF370, Section 87 of 167 of the complete genome" DATABASE Accession No. AE006558.	
		GLASER et al., "Genome sequence of Streptococcus agalactiae, a pathogen causing invasive neonatal disease," Mol. Microbiol. 45, 1499-1513, 2002	
		GRANDI & ZAGURSKY, "The impact of genomics in vaccine discovery: achievements and lessons," Expert. Rev. Vaccines 3, 621-23, 2004	
		Grandi, "Genomics and Proteomics in Reverse Vaccines," in <u>Microbial Proteomics: Functional Biology of Whole Organisms</u> , Humphery-Smith & Hecker, eds., John Wiley & Sons, chapter 20, 2006	
		GREENSPAN et al., "Defining epitopes: It's not as easy as it seems," Nature Biotechnol. 7, 936-37, 1999	
		GUTEKUNST et al., "Analysis of RggB-Controlled Virulence Mechanisms and Gene Expression in <i>Streptococcus agalactiae</i> ," Inf. Immun. 71, 5056-64, September 2003	
		GUTIERREZ et al., "insertional Mutagenesis and Recovery of Interrupted Genes of Streptococcus mutans by Using Transposon Tn917: Preliminary Characterization of Mutants Displaying Acid Sensitivity and Nutritional Requirements," J. Bacteriol. 178, 4166-75, July 1996	
		GUTIERREZ et al., "Streptococcus mutans ProX (pouABC) gene, partial cds; YlxM (ylxM) gene, complete cds; Ffh (ffh) gene, complete cds, alternatively spliced; SatC (satC) and SatD (satD) gene, complete cds; and SatE (satE) gene, partial cds," GENBANK Accession No. U88582, April 3, 2001	

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		GUZMAN et al., "Protective immune response against Streptococcus pyogenes in mice after intranasal vaccination with the fibronectin-binding protein SfbI," J. Infectious Disease 179, 901-06, 1999	
		HOLMES, "PSMA specific antibodies and their diagnostic and therapeutic use," Exp. Opin. Invest. Drugs 10, 511-10, 2001	
		HONG, "unnamed protein product [Streptococcus pyogenes]," NCBI Accession No. BAB1603, one page, Oct. 3, 2000	
		HORVATH et al., "Toward the development of a synthetic group a streptococcal vaccine of high purity and broad protective coverage," J Med Chem. 2004 Jul 29;47(16):4100-4	
		HUGHS et al., "Identification of Major Outer surface Proteins of <i>Streptococcus agalactiae</i> ," Inf. Immun. 70, 1254-59, March 2002	
		International Preliminary Examination Report for PCT/GB01/04789 (published as WO 02/34771) dated February 17, 2003	
		International Preliminary Examination Report for PCT/GB2003/001882 (published as WO 03/093306) dated August 18, 2004	
		International Preliminary Examination Report for PCT/US2005/036009 (published as WO 06/042027) dated April 11, 2007	
		International Preliminary Examination Report for PCT/US2003/029167 (published as WO 04/041157) dated March 5, 2005	
		International Preliminary Examination Report for PCT/US2004/024868 (published as WO 05/032582) dated February 6, 2006	

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		International Preliminary Examination Report for PCT/US2004/030032 (published as WO 05/028618) dated March 16, 2006	
		International Search Report for PCT/GB01/04789 (published as WO 02/34771) dated August 27, 2002	
		International Search Report for PCT/GB2003/001882 (published as WO 03/093306) dated November 14, 2002	
		International Search Report for PCT/US2005/036009 (published as WO 06/042027) dated June 20, 2006	
		International Search Report for PCT/US05/046491 dated June 26, 2007 (published as WO 2006/069200)	
		International Search Report for PCT/US2003/029167 (published as WO 04/041157) dated August 2, 2004	
		International Search Report for PCT/US2004/024868 (published as WO 05/032582) dated October 28, 2005	
		International Search Report for PCT/US2004/030032 (published as WO 05/028618) dated December 6, 2005	
		International Search Report for PCT/US2005/027239 (published as WO 06/078318) dated August 25, 2008	
		International Search Report for PCT/US2007/022838 (published as WO 08/108830) dated October 9, 2008	

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		JOBLING et al., "Analysis of structure and function of the B subunit of cholera toxin by the use of site-directed mutagenesis," Mol. Microbiol. 5, 1755-67, 1991	
		KALMAN et al., "Comparative genomes of Chlamydia pneumoniae and C. trachomatis," Nature Genetics 21, 385-89, April 1999	
		KEHOE et al., "Nucleotide Sequence of the Streptolysin O (SLO) Gene: Structural Homologies between SLO and Other Membrane-Damaging, Thiol-Activated Toxins," Inf. Immun. 55, 3228-32, December 1987	
		KOCH et al., "Complexity and expression patterns of the desmosomal adherins," Proc. Natl. Acad. Sci. USA 89, 353-57, January 1992	
		KUNST et al., "The complete genome sequence of the Gram positive bacterium Bacillus subtilis," NCBI Accession No. CAB14964, November 20, 1997	
		LACHENAUER et al., "A protective surface protein from the Type V Group B Streptococcus shares N-terminal sequence homology with the Alpha C Protein," Inf. Immun. 64, 4255-60, October 1996	
		LARSSON et al., "Protection against experimental infection with group B streptococcus by immunization with a bivalent protein vaccine," Vaccine 17, 454-58, 1999	
		LAUER et al., "Genome Analysis Reveals Pili in Group B Streptococcus," Science 309, 105, July 1, 2005	
		LAZAR et al., "Transforming growth factor alpha: mutation of aspartic acid 47 and leucine 48 results in different biological activities," Mol. Cell. Biol. 8, 1247-52, 1988	
		LE PAGE et al., "Streptococcus agalactiae sequence 217 from WO 01/32882, GENBANK Accession No. AX134653, May 29, 2001	

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		LEI et al., "Identification and immunogenicity of group A streptococcus culture supernatant proteins," <i>Inf. Immunity</i> 68, 6807-18, 2000	
		LEWIS, "Riddle of Biofilm Resistance," <i>Antimicrobial Agents and Chemotherapy</i> , Vol. 45, No. 4, pp. 999-1007, April 2001	
		LINDAHL et al., "Surface proteins of Streptococcus agalactiae and related proteins in other bacterial pathogens," <i>Clinical Microbiol. Rev.</i> 18(1), 102-07, Jan. 2005	
		MADOFF et al., "Maternal Immunization of Mice with Group B Streptococcal Type III Polysaccharide-Beta C Protein Conjugate Elicits Protective Antibody to Multiple Serotypes," <i>J. Clinical Invest.</i> 94, 286-92, 1994	
		MAIONE et al., "Identification of a Universal Group B <i>Streptococcus</i> Vaccine by Multiple Genome Screen," <i>Science</i> 309, 148-50, July 1, 2005	
		McMILLAN et al., "Identification and assessment of new vaccine candidates for group A streptococcal infections," <i>Vaccine</i> 22, 2783-90, 2004	
		McMILLAN et al., "Prospecting for new group A streptococcal vaccine candidates," <i>Indian J. Med. Res.</i> 119, 121-25, May 2004	
		MEEHAN & OWEN, "Sequence 1 from Patent WO9801561," GENBANK Accession No. A68631, May 6, 1999	
		MEINKE et al., "S. pyogenes hyperimmune system reactive antigen Spy0269," EBI Accession No. ADR83896, December 2, 2004; revised June 15, 2007	
		MICHEL et al: "Cloned alpha and beta C-protein antigens of group B Streptococci elicit protective immunity"; <i>INFECTION AND IMMUNITY</i> ; vol. 59, no. 6, June 1991; pp 2023-2028.	

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STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/527,672
Filing Date	April 18, 2006
First Named Inventor	RAPPUOLI
Group Art Unit	1645
Examiner Name	Devi
Attorney Docket Number	002441.00121

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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		MOLLING et al., "Naked DNA for vaccine or therapy," J. Mol. Med. 75, 242-46, 1997	
		MORA et al., "Group A Streptococcus produce pilus-like structures containing protective antigens and Lancefield T antigens," Proc. Natl. Acad. Sci. USA 102, 15641-46, October 25, 2005	
		MUSSER, "The Next Chapter in Reverse Vaccinology," Nat. Biotechnol. 24, 157-58, 2006	
		NAKAGAWA et al., "Genome sequence of an M3 strain of Streptococcus pyogenes reveals a large-scale genomic rearrangement in invasive strains and new insights into phage evolution," <i>Genome Res.</i> 13, 1042-55, June 2003	
		NAKATA et al., "MsmR, a specific positive regulator of the Streptococcus pyogenes FCT pathogenicity region and cytolysin-mediated translocation system genes," Mol. Microbiol. 57, 786-803, 2005	
		NAVARRE et al., "Surface Proteins of Gram-Positive Bacteria and Mechanisms of Their Targeting to the Cell Wall Envelope," <i>Microbiology and Molecular Biology Reviews</i> , Vol. 63, No. 1, pp. 174-229, March 1999	
		NCBI News, table on page 4, "Microbial Genomes Available for BLAST Search," July 1998	
		OLIVE et al., "Protection of mice from group A streptococcal infection by intranasal immunization with a peptide vaccine that contains a conserved M protein B cell epitope and lacks a T cell autoepitope," Vaccine 20, 2816-25, 2002	
		OREFICI et al., "Possible virulence marker for Streptococcus agalactiae (Lancefield Group B)," J. Clin. Microbiol. Infectious Diseases 7, 302-05, 1988	

Examiner
SignatureDate
Considered

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FOREIGN PATENT DOCUMENTS

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		PAOLETTI, "Surface structure of group B streptococcus important in human immunity," in <u>Gram Positive Pathogens</u> , Fischetti et al., eds., Chapter 14, pp. 137-53, 2000	
		POURNARAS et al., "Pheromone responses and high-level aminoglycoside resistance of conjugative plasmids of Enterococcus faecalis from Greece," J. Antimicrobial Chemotherapy 46, 1013-16, 2000	
		PRITZLAFF et al., "Genetic basis for the beta-haemolytic cytolitic activity of group B streptococcus," Mol. Microbiol. 39, 236-48, 2001	
		PRITZLAFF et al., "Streptococcus agalactiae cyl gene cluster, partial sequence," GENBANK Accession No. AF157015, February 8, 2001.	
		PROFT et al., "Identification and Characterization of Novel Superantigens from Streptococcus pyogenes," J. Exp. Med. 189, 89-101, January 4, 1999	
		PUCCI et al., "Enterococcus faecalis strain A24836 cell wall/cell division gene cluster, yllB, yllC, yllD, pbpC, mraY, murD, murG, divlB, ftsA and fitsZ genes, complete cds," GENBANK Accession No. U94707, September 10, 1997	
		QUINN, "The response of rheumatic and non-rheumatic children to streptolysin O concentrate," J. Clin. Invest. 36, 793-802, June 1957	
		RAMACHANDRAN et al., "Two Distinct Genotypes of prtF2, Encoding a Fibronectin Binding Protein, and Evolution of the Gene Family in Streptococcus pyogenes," Journal of Bacteriology, Vol. 186, No. 22, pp. 7601-7609, November 2004	
		RODEWALD et al., "Neonatal mouse model of group b streptococcal infection," J. Infectious Diseases 166, 635-39, 1992	

Examiner
Signature

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Considered

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		RODRIGUEZ-ORTEGA et al., "Characterization and identification of vaccine candidate proteins through analysis of the group A Streptococcus surface proteome," Nature Biotechnol. 24, 191-97, 2006	
		ROITT et al., Structure of Antigens, <u>Immunology</u> , 4th ed., Mosby, London, pages 7.7 and 7.8, 1998	
		ROSINI et al., "Identification of novel genomic islands coding for antigenic pilus-like structures in Streptococcus agalactiae," Mol. Microbiol. 61, 126-41, 2006	
		RUDENKO et al., "Selection for activation of a new variant surface glycoprotein gene expression site in Trypanosoma brucei can result in deletion of the old one," Mol. Biochem. Parasitol. 95, 97-109, 1998; NCBI Accession No. CAD21770	
		RUDINGER et al., "Characteristics of the amino acids as components of a peptide hormone sequence," in <u>Peptide Hormones</u> , Parsons, ed., University Park Press, June 1976, pages 1-7	
		SCHNEEWIND et al., "Sequence and Structural Characteristics of the Trypsin-Resistant T6 Surface Protein of Group A Streptococci," <u>Journal of Bacteriology</u> , Vol. 172, No. 6, pp. 3310-3317, June 1990	
		SCHNEEWIND, "Structure of the Cell Wall anchor of Surface Proteins in Staphylococcus aureus," Science 268, 103-06, April 7, 1995	
		SEGURA et al., "Streptococcus suis and group B Streptococcus differ in their interactions with murine macrophages," FEMS Immunol. Med. Microbiol. 21, 189-95, 1998	
		SEIZEN, "Multi-domain, cell envelope proteases of lactic acid bacteria," Antonie von Leeuwenhoek 76, 139-55, 1999	
		SIMPSON et al., "Xylella fastidiosa 9a5c, section 136 of 229 of the complete genome," GENBANK Accession No. AE003990, June 4, 2004	

Examiner
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		SMOOT <i>et al.</i> , "Genome sequence and comparative microarray analysis of serotype M18 group A Streptococcus strains associated with acute rheumatic fever outbreaks," <i>Proc. Natl. Acad. Sci. USA</i> 99, 4668-73, April 2, 2002	
		SPELLERBERG <i>et al.</i> , "Streptococcus agalactiae cyl gene cluster, complete sequence," GENBANK Accession No. AF093787, July 31, 2000	
		SPELLERBERG <i>et al.</i> : "Identification of genetic determinants for the hemolytic activity of Streptococcus agalactiae by ISSI transposition"; J. BACTERIOL.; vol. 181, no. 10, May 1999; pp 3212-3219.	
		STALHAMMAR-CARLEMALM <i>et al.</i> : "The R28 Protein of Streptococcus pyogenes is related to several group B streptococcal surface proteins, confer protective immunity and promotes binding to human epithelial cells"; Mol. Microbiol. 1, July 1999, pp 208-219.	
		STEPHENSON <i>et al.</i> , "The Fap1 fimbrial adhesin is a glycoprotein: antibodies specific for the glycan moiety block the adhesion of <i>Streptococcus parasanguis</i> in an <i>in vitro</i> tooth model," <i>Mol. Microbiol.</i> 43, 147-57, 2002	
		SU <i>et al.</i> , "Identification of a <i>Xenopus</i> cDNA that prevents mitotic catastrophe in the fission yeast <i>Schizosaccharomyces pombe</i> ," <i>Gene</i> 145, 155-56, 1994	
		Supplementary Search report for EP 03799822 (corresponding to WO 04/041157) dated January 21, 2008	
		SUROVOV & FERRETTI, "Physical and Genetic Chromosomal Map of an M Type 1 Strain of Streptococcus pyogenes," J. Bacteriol. 178, 5546-49, September 1996	
		TAKAMI <i>et al.</i> , "Two component sensor histidine kinase involved in phosphate regulation," NCBI Accession No. NP_244022.1, September 10, 2001	

Examiner
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		TELFORD et al., "Sequence 7466 from WO 02/34771, EBI Accession No. CQ650509, February 2, 2004; modified May 31, 2006	
		TELFORD et al., "Streptococcus polypeptide SEQ ID NO 9188" of WO 02/34771, EBI Accession No. ABP300006, July 2, 2002; revised June 15, 1007	
		TETTELIN et al., "Complete genome sequence and comparative genomic analysis of an emerging human pathogen, serotype V Streptococcus agalactiae," Proc. Natl. Acad. Sci. USA 99, 12391-96, September 17, 2002	
		TETTELIN et al., "Complete genome sequence of a virulent isolate of Streptococcus pneumoniae," Science 293, 498-506, 2001	
		TETTELIN et al., DATABASE EMBL, Accession No. AE014193, Streptococcus agalactiae 2603V/R section 3 of 100 of the complete genome, September 2, 2002	
		TETTELIN et al., Swiss-Prot Accession No. Q3DV91 for Streptococcus agalactiae strain 18R21, November 22, 2005	
		TIGHE et al., "Gene vaccination: plasmid DNA is more than just a blueprint," Immunology Today 19, 89-97, Feb. 1998	
		TODD, "Antigenic Streptococcal Hemolysin," J. Exp. Med. 55, 267-80, 1932	
		TON-THAT & SCHNEEWIND, "Assembly of pili on the surface of Corynebacterium diphtheriae," Mol. Microbiol. 50, 1429-38, 2003	
		TON-THAT et al., "Sortases and pilin elements involved in pilus assembly of Corynebacterium diphtheriae," Mol. Microbiol. 53, 251-61, 2004	

Examiner
SignatureDate
Considered

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		UniProt Accession No. A7CNQ7, July 5, 2004	
		UniProt Accession No. Q5XEL1, Nov. 23, 2004	
		UniProt Accession No. Q8P318, Oct. 1, 2002	
		VALLET <i>et al.</i> , "The chaperone/usher pathways of <i>Pseudomonas aeruginosa</i> : Identification of fimbrial gene clusters (cup) and their involvement in biofilm formation," <i>PNAS</i> , Vol. 98, No. 12, pp. 6911-6916, June 2001	
		WANG <i>et al.</i> , "Protein encoded by prokaryotic essential gene #31978," EBI Accession No. ABU46451, June 19, 2003; revised June 15, 2007	
		WATNICK <i>et al.</i> , "Steps in the development of a <i>Vibrio cholerae</i> El Tor biofilm," <i>Molecular Microbiology</i> , Vol. 34, No. 3, pp. 586-595, 1999	
		WOODSON <i>et al.</i> , "Analysis of a ribose transport operon from <i>Bacillus subtilis</i> ," <i>Microbiology</i> 140, 1829-38, 1994	
		ZHONG <i>et al.</i> , "Hypothetical protein of <i>Arabidopsis thaliana</i> ," NCBI Accession No. AAD29767, May 11, 1999	

Examiner
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		Number - Kind Code ² (if known)			
		4454121	06-12-1984	Beachey	
		5098827	03-24-1992	Boyle et al.	
		5354846	10-11-1994	Kehoe	
		5378620	01-03-1995	Adams et al.	
		5391712	02-21-1955	Adams et al.	
		5445820	08-29-1995	Seidel et al.	
		5585098	12-17-1996	Coleman	
		5700648	12-23-1997	Kehoe	
		5821088	10-13-1998	Darzins et al.	
		5846547	12-08-1998	Cleary	
		5968763	10-19-1999	Fischetti et al.	
		6174528	01-16-2001	Cooper et al.	
		6406883	06-18-2002	Lutticken et al.	
		6420152	07-16-2002	Adams et al.	
		6579711	06-17-2003	Gaier et al.	
		6635623	10-21-2003	Hoogeveen et al.	
		6669703	12-30-2003	Shue	
		6737521	05-18-2004	Fischetti et al.	
		6747437	06-08-2004	Chiu	
		6777547	08-01-2004	Podbielski	
		6833356	12-21-2004	Koenig et al.	
		6936252	08-30-2005	Gilbert et al.	
		7033765	04-25-2006	Dime et al.	
		7041814	05-09-2006	Weinstock et al.	
		7098182	08-29-2006	Le Page et al.	
		7101692	09-05-2006	Schneewind et al.	
		7128918	10-31-2006	Hamel et al.	
		7128919	10-31-2006	Adderson et al.	
		7169902	01-30-2007	Podbielski	
		7247308	07-24-2007	Martin et al.	
		7348006	03-25-2008	Contorni et al.	
		7407664	08-05-2008	Beall et al.	
		7438912	10-21-2008	Meinke et al.	
		7485710	02-03-2009	Reinscheid et al.	

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		Number - Kind Code ² (if known)			
		20020025516	02-28-2002	Black et al.	
		20020045737	04-18-2002	Choi et al.	
		20020061569	05-23-2002	Haselbeck et al.	
		20020086023	07-04-2002	Dale	
		20030035805	02-20-2003	Michel et al.	
		20030109690	06-12-2003	Ruben et al.	
		20030157122	08-21-2003	Dale	
		20030171337	09-11-2003	Aylward et al.	
		20040029129	02-12-2004	Wang et al.	
		20040101536	05-27-2004	Teti et al.	
		20040219639	11-04-2004	Potter et al.	
		20040236072	11-25-2004	Olmsted et al.	
		20050019345	01-27-2005	Podbielski	
		20050020813	01-27-2005	Masignani et al.	
		20050181388	08-18-2005	Edwards et al.	
		20050214918	09-29-2005	Edwards et al.	
		20050288866	12-29-2005	Sachdeva	
		20060039922	02-23-2006	Mizzen et al.	
		20060041961	02-23-2006	Abad et al.	
		20060073530	04-06-2006	Schneewind et al.	
		20060115479	06-01-2006	Reinscheid et al.	
		20060160121	07-20-2006	Mounts et al.	
		20060165716	07-27-2006	Telford et al.	
		20060194751	08-31-2006	Meinke et al.	
		20060210579	09-21-2006	Telford et al.	
		20060210580	09-21-2006	Telford et al.	
		20060210581	09-21-2006	Telford et al.	
		20060210582	09-21-2006	Telford et al.	
		20060258849	11-16-2006	Telford et al.	
		20060269541	11-30-2006	Meinke et al.	
		20060275315	12-07-2006	Telford et al.	
		20070036828	02-15-2007	Rappuoli et al.	
		20070053924	03-08-2007	Tettelin et al.	
		20070065464	03-22-2007	Grandi et al.	
		20070098737	05-03-2007	Dale	
		20070116712	05-24-2007	Hamel et al.	

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U.S. PATENT DOCUMENTS

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		EP0369825	05-23-1990	Kehoe		
		EP0613947	01-31-1994	Beckman-Coulter Inc.		
		EP1770171	04-04-2007	Universität zu Köln		
		EP555438	01-22-1997	Beckman Instruments		
		EP555439	10-15-1997	Beckman Instruments		
		GB2233977	01-23-1991	Kehoe		
		WO199006951	06-28-1990	Paton		
		WO199305155	03-18-1993	Beckman Instruments		
		WO199305156	03-18-1993	Beckman Instruments		
		WO199801561	01-15-1998	Trinity College, Dublin		
		WO199803677	08-1998	Dime		
		WO199818931	05-07-1998	Kunsch et al.		
		WO199819689	05-14-1998	SmithKline Beecham		
		WO199823631	06-04-1998	SmithKline Beecham		
		WO199954457	10-28-1999	Chiron Spa		
		WO199913084	03-18-1999	Dale		
		WO199916882	04-08-1999	Medimmune, Inc.		
		WO199926969	06-03-1999	University of Otago; New Zealand Pastoral Agriculture Research Institute Limited		
		WO199942588	08-26-1999	Biochem. Vaccines Inc.		
		WO200006736	02-10-2000	Le Page		
		WO200006737	02-10-2000	Gilbert et al.		
		WO200023456	04-27-2000	Scripps Research Institute		
		WO200062804	10-26-2000	Regents of the University of California		
		WO200078787	12-28-2000	University of Utah Research Foundation		
		WO200132882	05-10-2001	Microbial Technics Ltd.		
		WO2002012294	02-14-2002	St. Jude Children's Research Hospital		
		WO2002075507	09-26-2002	Pharmacia & UpJohn		
		WO2002077183	10-03-2002	Elitra Pharmaceuticals Inc.		
		WO2002092818	11-21-2002	Institute Pasteur		
		WO2003068813	08-21-2003	Shire Biochem. Inc.		

Examiner
SignatureDate
Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 20 of 20

Complete if Known

Application Number	10/527,672
Filing Date	April 18, 2006
First Named Inventor	RAPPUOLI
Group Art Unit	1645
Examiner Name	Devi
Attorney Docket Number	002441.00121

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO2003087353	10-23-2003	Affinium Pharmaceuticals Ltd.		
		WO2003093306	11-13-2003	Chiron Srl & TIGR		
		WO2004018646	03-04-2004	Chiron Corp. & TIGR		
		WO2004035618	03-31-2004	Chiron Corporation		
		WO2004078907	09-16-2004	Intercell AG		
		WO2004099242	11-18-2004	Intercell AG		
		WO2005013666	02-17-2005	Garvan Institute for Medical Research		
		WO2005028618	03-31-2005	Chiron Corporation		
		WO2005032582	04-14-2005	Chiron Corporation		
		WO2005076010	08-18-2005	Council of Scientific and Industrial Research New Delhi		
		WO2005108419	11-17-2005	University of Glasgow		
		WO2006035311	04-06-2006	Chiron Srl		
		WO2006042027	04-20-2006	Chiron Corporation		
		WO2006069200	06-29-2006	Chiron Corporation		
		WO2006078318	07-27-2006	Chiron Corporation		
		WO2006082527	08-10-2006	Chiron Srl		
		WO2006082530	08-10-2006	Chiron Srl		
		WO2006130328	12-07-2006	Novartis Vaccines and Diagnostics, Inc.		
		WO2007018563	02-15-2007	Wyeth		
		WO2007039319	04-12-2007	Universität zu Köln		
		WO2007052168	05-10-2007	Novartis Vaccines and Diagnostics Srl		
		WO2008003515	10-01-2008	Intercell		
		WO2008020335	02-21-2008	Novartis AG		
		WO2008108830	09-12-2008	Novartis AG		

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Considered

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